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The right to health

Note by the Secretary-General

The Secretary-General has the honour to transmit to the General Assembly the interim report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Paul Hunt, submitted in accordance with Human Rights Council resolution 6/29.

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Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health

Summary

The present report, submitted in accordance with Human Rights Council resolution 6/29, contains two main sections: as accountability is one of the central features of human rights, section I discusses the importance of effective, transparent, accessible and independent accountability mechanisms in relation to the right to the highest attainable standard of health. Section II and the annex to the present report, containing the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, which set out the human rights responsibilities of pharmaceutical companies in that context. Each theme is accompanied by a Commentary. The product of wide-ranging discussions spanning five years, the Guidelines consider issues such as transparency, management, accountability, patents, licensing and pricing.

Since this is the last thematic report of Mr. Hunt, it concludes with some brief observations arising from his tenure between 2002 and 2008.

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I. Introduction

1. The mandate of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health ("the right to the highest attainable standard of health" or "the right to health") was established pursuant to Commission on Human Rights resolutions 2002/31 and 2004/27. By its resolution 6/29 of 14 December 2007, the Human Rights Council extended the mandate of the Special Rapporteur for a further period of three years. The present report is submitted in accordance with that resolution.

II. Activities of the mandate

2. In accordance with his mandate, the Special Rapporteur has been considering the policies and practices of pharmaceutical companies in relation to the right to the highest attainable standard of health, including access to medicines. In that context, the Special Rapporteur was invited to undertake a visit to a pharmaceutical company, GlaxoSmithKline on 2 and 3 June 2008. The main objective of the mission was to review the policies of that company and learn about good practices, as well as obstacles encountered by the company in relation to the right to the highest attainable standard of heath. The report will be submitted to the Human Rights Council in 2009.

3. On 5 June 2008, the Human Rights Council devoted a full day's meeting to the human rights of women. The purpose of the meeting was to give an overview of the work of other United Nations bodies and agencies regarding the human rights of women. The Special Rapporteur participated in the panel on maternal mortality that was designed to raise awareness of maternal mortality as a human rights issue. Participants discussed a wide range of issues, including sexual and reproductive health rights; the importance of education and awareness-raising on sexual and reproductive health issues; access to contraception, emergency obstetric care and other health services; the relationship between maternal mortality and unsafe abortion; the importance of increasing donor support for maternal health; and the critical importance of monitoring and accountability, such as maternal death audits or reviews.

4. Between January and July 2008, the Special Rapporteur participated in a number of meetings convened by international organizations, Governments, civil society and others. In February, he spoke at a conference, organized by the Northern Ireland Human Rights Commission, on health and human rights. Also in February, he spoke to the staff of the leading medical journal, *The Lancet*. In March, he travelled to Washington, D.C., and made a presentation to the Pan-American Health Organization (PAHO) on "Looking at the PAHO Strategic Plan 2008-2012 from a human rights perspective". While in Washington, he was invited to the 131st regular session of the Inter-American Commission on Human Rights to participate in a right-to-health discussion with the Commissioners and other specialists. In March, the Special Rapporteur delivered a paper, on health and human rights impact assessments, as part of a seminar series organized by London Metropolitan University. During the same month he also delivered a keynote address at an African HIV/AIDS Conference in London. In April he made a presentation on palliative care and human rights to the Help the Hospices International Palliative Care Reference Group. In April, he spoke on the right to the highest attainable standard of health at

a London seminar organized by the Society of Legal Scholars. At the end of April, he travelled to New York, where he had a series of meetings. He met with Realizing Rights: The Ethical Globalization Initiative to discuss the draft "Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines", as well as the work of the GAVI Alliance. While in New York, the Special Rapporteur spoke at a meeting organized by the People's Health Movement (United States of America). In May 2008, he delivered the opening address in Barcelona at the 19th International Conference on the Reduction of Drug Related Harm, organized by the International Harm Reduction Association. The Association has now published his presentation which is entitled "Human rights, health and harm reduction: States' amnesia and parallel universes" (see www.ihra.net). The Special Rapporteur also delivered a keynote address at the 2nd Conference on Migrant Health in Europe, held in Malmo, Sweden, on 23 and 24 May 2008

5. Reports relating to the Special Rapporteur's missions to Ecuador/Colombia and India, and as well as GlaxoSmithKline will be submitted to the Human Rights Council in 2009.

6. In the reporting period, the Special Rapporteur sent a number of urgent appeals and other communications to various Governments. The communications will be reflected in the communications report that will be submitted to the Human Rights Council in 2009.

7. All United Nations documents related to the work of the Special Rapporteur, including press statements and reports to the General Assembly and the Commission on Human Rights/Human Rights Council, are available on the website of the Office of the High Commissioner for Human Rights (www.ohchr.org). For ease of reference, all the Special Rapporteur's official reports and press statements, as well as selected conference papers, presentations and interviews, can be found on the website of the Human Rights Centre, University of Essex (www2.essex.ac.uk/human_rights_centre/rth.shtm).

III. Accountability

8. Accountability is one of the central features of human rights. Without accountability, human rights can become no more than window-dressing. Whether human rights are applied to development, poverty reduction, trade, health systems, neglected diseases, maternal mortality, HIV/AIDS or anything else, they require that accessible, transparent and effective mechanisms of accountability be established.

9. Accountability provides individuals and communities with an opportunity to understand how those with human rights responsibilities have discharged their duties. Equally, it provides those with human rights responsibilities the opportunity to explain what they have done and why. Where mistakes have been made, accountability requires redress. But accountability is not a matter of blame and punishment. Sometimes called constructive accountability, it is a process that helps to identify what works, so that it can be repeated, and what does not, so that it can be revised. It is a way of checking that reasonable balances are fairly struck.

10. Although human rights demand accountability, that does not mean that everybody working in health and human rights — all health professionals, all specialized agencies — have the task of holding duty-bearers to account. The health

and human rights movement needs human rights advisers, implementers and enablers, as well as those whose job it is to hold duty-bearers to account. All those functions will rarely reside in one organization or individual. For example, while specialized agencies should be human rights advisers, implementers and enablers, it is not their primary task to hold States to account. The accountability function must be provided by some organization or person, but probably not by a specialized agency, unless the agency decides to establish a discreet independent procedure and body for this purpose.[1]

11. In the context of the right to the highest attainable standard of health, there are many different types of accountability mechanisms, including national human rights institutions, health commissioners, democratically elected local health councils, public hearings, patients' committees, impact assessments, judicial proceedings, and others. An institution as complex and important as a health system — and a human right as complex and extensive as the right to the highest attainable standard of health — require a range of effective, transparent, accessible, independent accountability mechanisms. The media and civil society organizations have a crucial role to play.

12. Accountability in respect of health systems is often extremely weak. Sometimes the same body that provides health services also deals with regulating and holding to account. In some cases, accountability is little more than a device to check that health funds were spent as they should have been. Of course, that is important. But human rights accountability is much broader. It is also concerned with ensuring that health systems are improving, and the right to the highest attainable standard of health is being progressively realized, for all, including disadvantaged individuals, communities and populations.

13. In some States, the private health sector, while playing a very important role, is largely unregulated. Crucially, the requirement of human rights accountability extends to both the public and private health sectors. Additionally, it is not confined to national bodies; it also extends to international actors working on health-related issues. Accountability mechanisms are urgently needed for all those — public, private, national and international — working on health-related issues.

14. The design of appropriate, independent accountability mechanisms demands creativity and imagination. Often associated with accountability, lawyers must be willing to understand the distinctive characteristics and challenges of the right to the highest attainable standard of health, and learn from the rich experience of medicine and public health.

15. Since 2002, the Special Rapporteur has emphasized the critical importance of accountability in relation to the right to the highest attainable standard of health. Building on the work of others, he has developed an analytical framework for "unpacking" the right to health and making this fundamental human right easier to grasp. This analytical framework is used in most of his reports. Crucially, monitoring and accountability are an integral part of this framework.[2]

16. Judicial accountability is one form of accountability. While this form of accountability is considered in many of the Special Rapporteur's reports, the most

[1] As the International Labour Organization has chosen to do.

[2] One of the fullest elaborations of the analytical framework is in the report on people with mental disabilities (E/CN.4/2005/51); on monitoring and accountability, see paras. 67-75.

detailed discussion is in A/HRC/4/28 (section III). There are also administrative forms of accountability, such as health impact assessments, explored in A/62/214 (section III). The Special Rapporteur's reports on the skills drain (A/60/348, paras. 66-72 and 86-88), the Millennium Development Goals (A/59/422, paras. 36-41), and health systems (A/HRC/7/11 and Corr.1, paras. 65 and 99-106) have also addressed accountability. Further, the Special Rapporteur's country reports have frequently addressed accountability mechanisms, for example, in relation to Uganda (E/CN.4/2006/48/Add.2, paras. 86-93), Romania (E/CN.4/2005/51/Add.4, paras. 26-27) and Sweden (A/HRC/4/28/Add.2, paras. 31-33 and 122-123). The Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines (see annex to the present report) also look at the critical issue of accountability of pharmaceutical companies.

17. On the whole, however, the human rights literature devotes surprisingly little attention to accountability — and there is even less written about accountability and the right to the highest attainable standard of health. Thus, a recent study by Helen Potts, *Accountability and the Right to the Highest Attainable Standard of Health*[3] (see www2.essex.ac.uk/human_rights_centre/rth) is very timely. This practical study introduces the right to the highest attainable standard of health; describes the process of accountability (which includes monitoring, holding to account, and redress); provides examples of various accountability mechanisms that are available at the national, regional and international levels; describes the types of remedies that should be available to rights-holders; provides examples of accountability in action; and provides a list of key factors required for accountability in the context of the right to the highest attainable standard of health.

18. The study is a valuable information resource for all those committed to health and human rights, including policymakers and advocates. It will help Governments to fulfil their right-to-health obligations and assist those seeking to hold Governments to account. The Special Rapporteur hopes that this useful study will generate more research and publications, as well as a deeper appreciation of the crucial role of accountability and the right to the highest attainable standard of health.

IV. The human rights responsibilities of pharmaceutical companies in relation to access to medicines

19. States have primary responsibility for enhancing access to medicines. Between 2002 and 2008, the Special Rapporteur regularly scrutinized States' duties in relation to access to medicines. These duties are the main focus of chapter III.A of his report to the General Assembly at its sixty-first session (A/61/338). They are also a key theme recurring throughout several of his country missions and reports, such as those regarding Peru (E/CN.4/2005/51/Add.3) and Uganda (E/CN.4/2006/48/Add.2). Another report looks at States' duties in relation to access to medicines and the World Trade Organization (E/CN.4/2004/49/Add.1). Some of his press statements have focused on States' duties in relation to access to medicines, for example, the press remarks of 5 July 2004 and 13 July 2005. In

[3] University of Essex, 2008, funded by the Open Society Institute.

addition, some of his other publications have examined States' duties in relation to access to medicines, such as "Neglected diseases: A human rights analysis".[4]

20. Moreover, the Special Rapporteur has frequently discussed access to medicines with States, including the adverse impact of import tariffs on access, the enormous problem of failing and collapsing health systems, counterfeiting, diversion, and so on. He has provided States with numerous recommendations regarding access to medicines and he has also commented when, in his view, States have failed to do all they reasonably can to enhance access to this vital component of the right to the highest attainable standard of health.

21. In short, States have been the central focus of his attention in relation to access to medicines.

22. On numerous occasions over the last six years, Ministers, senior public officials and others have informed the Special Rapporteur that, when endeavouring to implement the right to the highest attainable standard of health, States encounter many obstacles. Among the obstacles they have mentioned, two stand out. First, the policies and practices of donor countries; for this reason, the Special Rapporteur has looked, on numerous occasions in several reports, at the role of donors, most recently in his report on his mission to Sweden, the World Bank and the International Monetary Fund (A/HRC/7/11/Add.2).

23. Secondly, Ministers, senior public officials and others have argued that the policies and practices of some pharmaceutical companies constitute obstacles to States' implementation of the right to the highest attainable standard of health and, in particular, their endeavours to enhance access to medicines. They have mentioned, for example, excessively high prices, inadequate attention to research and development concerning diseases that disproportionately impact people in developing countries, inappropriate drug promotion, and problematic clinical trials. Ministers and senior public officials have also acknowledged, however, that the pharmaceutical sector has an indispensable role to play in relation to the right to health and access to medicines. Moreover, they have recognized the constructive contribution of specific pharmaceutical companies.

24. The Special Rapporteur's mandate expressly requires him to identify, inter alia, obstacles to the implementation of the right to the highest attainable standard of health. He is also expressly mandated to report on good practices, and to make recommendations that will help to promote and protect the right to the highest attainable standard of health.

25. Between 2003 and 2006, the Special Rapporteur engaged in many discussions on access to medicines with numerous parties, including pharmaceutical companies. These substantive discussions took place at symposiums and workshops, as well as informal visits to pharmaceutical companies. They were informed by the work of States, pharmaceutical companies (and their associations, such as the International Federation of Pharmaceutical Manufacturers and Associations), the United Nations Global Compact, the Office of the High Commissioner for Human Rights, the World Health Organization and other elements of the United Nations system, the Business Leaders Initiative on Human Rights, numerous civil society organizations, and

[4] Paul Hunt et al., *Neglected diseases: A human rights analysis*, World Health Organization Special Programme for Research and Training, Special Topics No.6, 2007.

others. More recently, the Special Rapporteur has benefited from the reports of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises.

26. During these numerous discussions, the human rights duties of States in relation to access to medicines were reasonably clear, and these duties are now explored, in considerable detail, in the Special Rapporteur's various reports (see A/61/338). However, it became apparent during these discussions that the nature and scope of pharmaceutical companies' human rights responsibilities in relation to access to medicines were not clear. The Committee on Economic, Social and Cultural Rights, for example, confirms that the private business sector has responsibilities regarding the realization of the right to the highest attainable standard of health, but it has not taken further steps to specify these responsibilities.[5] While the Committee's general statement of principle is very important, it provides no practical guidance about the human rights responsibilities of pharmaceutical companies in relation to access to medicines.

27. It became imperative, therefore, to address this situation. How can pharmaceutical companies sensibly be asked to respect their human rights responsibilities in relation to access to medicines without much more specific guidance, as well as the identification of good practices? How can they be monitored, and held to account, if their human rights responsibilities in relation to access to medicines are unclear?

28. In an effort to shape a collaborative approach aimed at addressing these questions, a series of substantive meetings with a number of major pharmaceutical companies, and civil society groups, was organized by the Special Rapporteur and Mary Robinson, President of Realizing Rights: The Ethical Globalization Initiative and former High Commissioner for Human Rights. The result of these discussions was a two-phase proposal suggesting a way forward. This proposal was discussed at length with the companies involved and revised to accommodate a number of their concerns.

29. First, it was suggested that a small group of human rights experts and representatives from pharmaceutical companies work together to identify as much common ground as possible, as well as good faith disagreements, in relation to pharmaceutical companies' human rights responsibilities and access to medicines. It was proposed that this process would take two years and would generate an important, useful report that clarified what can properly be asked of pharmaceutical companies in relation to access to medicines and human rights.

30. The second part of the proposal outlined a process through which a small group of experts would then be appointed, by consensus among those participating in the initiative, to use this report to evaluate the policies and practices of certain pharmaceutical companies. These evaluations would be made public. This second phase would last for an initial period of three years.

31. The hallmark of this two-phase, five-year proposal was constructive cooperation and collaboration with a number of major pharmaceutical companies.

32. To their credit, two companies, Novartis and NovoNordisk, were willing to proceed with the proposal. Unfortunately, however, the majority of companies

[5] See E/C.12/2000/4, general comment 14, para. 42.

involved in the initiative were unwilling to proceed. Reluctantly, the Special Rapporteur and Mrs. Robinson decided that buy-in from only two companies was insufficient for what was designed to be a collaborative initiative engaging a range of major pharmaceutical companies. It was agreed that there was no choice, unfortunately, other than to put the proposal aside.

33. The regrettable refusal of some pharmaceutical companies to engage in this collaborative project did not diminish the need to pursue the central objective. Given that some States allege that the practices of some pharmaceutical companies are obstacles to access to medicines, the urgent need remained for greater clarity regarding the human rights responsibilities of pharmaceutical companies in relation to access to medicines.

34. Of course, the long-term goal is the development of internationally recognized human rights guidelines for both States and pharmaceutical companies in relation to access to medicines. However, there is greater clarity about the human rights responsibilities of States than there is about the responsibilities of pharmaceutical companies regarding access to medicines. As already observed, several reports of the Special Rapporteur explore the responsibilities of States regarding access to medicines. Indeed, one report applies the right-to-health analytical framework and sets out in detail the numerous human rights responsibilities of States in relation to access to medicines (A/61/338). There is no comparable human rights guidance for pharmaceutical companies in relation to access to medicines. In these circumstances, the Special Rapporteur's priority focus was on human rights guidelines for pharmaceutical companies in relation to access to medicines.

35. Thus, as signalled in his report to the General Assembly (ibid.), the Special Rapporteur embarked on a process of preparing, for consultation, draft human rights guidelines for pharmaceutical companies in relation to access to medicines. That process drew heavily upon the extensive discussions with pharmaceutical companies and others that had taken place between 2003 and 2006. There were additional consultations, too. In 2007, for example, the University of Toronto organized a multi-stakeholder workshop, attended by pharmaceutical companies.

36. That process led to the publication of draft guidelines in September 2007. The draft was available for public comment until 31 December 2007; to allow as much consultation as possible, the deadline was postponed until 31 March and again until 15 May 2008. To facilitate consultation, the draft was placed on the websites of the Office of the High Commissioner for Human Rights, as well as the Human Rights Centre, University of Essex. The Special Rapporteur noticed that the draft was also posted on numerous other websites, too.

37. Since September 2007, the Special Rapporteur actively sought comments on the draft. In October, the Government of Brazil held an open consultation, attended by States, at United Nations Headquarters in New York. There were two consultations with a number of major institutional investors in New York and in London. The draft was discussed with the World Health Organization and, on two occasions, with the International Federation of Pharmaceutical Manufacturers and Associations. Other non-governmental organizations were also consulted.

38. Unfortunately, when the Special Rapporteur approached some pharmaceutical companies to meet and discuss the draft, all declined, with the exception of NovoNordisk. Although the Special Rapporteur's mission in June 2008 to

GlaxoSmithKline (see para. 2 above) did not specifically examine the draft Guidelines, the mission provided an excellent occasion to reflect very closely on the issues, and the Special Rapporteur is most grateful for that opportunity. A few companies sent helpful written comments on the draft. Some 40 stakeholders sent written comments, all of which were placed on the web, with a small handful of exceptions where confidentiality was requested.

39. In summary, extensive written and oral comments on the draft were received from a very wide range of stakeholders encompassing States, institutional investors, pharmaceutical companies, specialized agencies, national human rights institutions, non-governmental organizations, academics, and others. The Special Rapporteur takes this opportunity to warmly thank all of those who provided their invaluable comments, advice and information. A special thank you is due to Realizing Rights: The Ethical Globalization Initiative. The Special Rapporteur, however, has sole responsibility for the draft and final version of the Guidelines.

40. When the Special Rapporteur informed the General Assembly in October 2006 that he intended to prepare draft guidelines, he was encouraged to proceed with this challenging project. He updated the Human Rights Council in March 2007 and the General Assembly in October 2007. When reporting to the Human Rights Council in March 2008, he confirmed his intention to finalize the text before the end of July 2008.

The Guidelines

41. The draft Guidelines were extensively revised in the light of the very numerous written and oral comments. The final version of the Guidelines is contained in the annex to the present report. Beginning with a preamble, the Guidelines are grouped by themes, such as transparency, management, monitoring and accountability, pricing and ethical marketing. Each theme is followed by a brief commentary.

42. The Guidelines should be read with the Special Rapporteur's report to the General Assembly on access to medicines (A/61/338). That report includes a section on the responsibilities of States and another on the responsibilities of pharmaceutical companies. The discussion and analysis will not be repeated here. Instead, some interrelated points are briefly emphasized.

Health systems

43. At the heart of the right to the highest attainable standard of health lies an effective and integrated health system, encompassing medical care and the underlying determinants of health, which is responsive to national and local priorities, and accessible to all. Medical care and access to medicines are vital elements of an effective, integrated, responsive and accessible health system. Their full realization crucially depends upon such a system being in place. In many countries, however, health systems are failing and collapsing (see A/HRC/7/11). There are, in many countries, extremely grave systemic obstacles to enhancing access to medicines, such as clinics without health workers and the most basic facilities. While immediate steps can be taken by a range of actors to enhance access to medicines, it is imperative that systemic obstacles are recognized and tackled as a matter of priority and urgency.

A shared responsibility

44. States have primary responsibility for ensuring both the right to the highest attainable standard of health and enhancing access to medicines. However, it is a shared responsibility. If access to medicines is to be enhanced, numerous national and international actors have an indispensable role to play. The Millennium Development Goals recognize that pharmaceutical companies are among those sharing this responsibility. Goal 8, a global partnership for development, has a number of targets, not least: "In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries".

Enhancing shareholder value

45. Pharmaceutical companies operate in complex market and social settings that give rise to a range of responsibilities to various stakeholders. Of course, companies have a responsibility to enhance shareholder value. This responsibility has to be seen in the context of other social, developmental and human rights responsibilities, especially the pharmaceutical sector's central societal mission to develop high-quality medicines that are accessible to those in need. Moreover, all pharmaceutical companies would find it beneficial to adopt a rights-sensitive approach to their businesses, as outlined in the excellent joint publication of the United Nations Global Compact, Business Leaders Initiative on Human Rights, and OHCHR.[6]

Practical, constructive guidance

46. The Guidelines do not use the peremptory word "must", but the more modest language "should". In other words, they deliberately avoid some of the most controversial doctrinal questions (such as, "are businesses legally bound by international human rights law?") that have dominated debates about business and human rights for many years. These discussions are important, and the Special Rapporteur has contributed to them elsewhere,[7] but the central objective of the Guidelines is to provide practical, constructive and specific guidance to pharmaceutical companies and other interested parties, including those who wish to monitor companies and hold them to account. The Guidelines are consistent with and complementary to the helpful analysis recently provided by the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises (A/HRC/8/5).

Key human rights standards upon which the Guidelines are based

47. The Guidelines are based on human rights principles that are enshrined in the Universal Declaration of Human Rights, including non-discrimination, equality, transparency, monitoring and accountability. The Guidelines are also informed by some features of the right to the highest attainable standard of health. As the Constitution of the World Health Organization affirms, "enjoyment of the highest attainable standard of health is one of the fundamental rights of every human

[6] See *A Guide for Integrating Human Rights into Business Management* available at www.blihr.org/.

[7] In his report at the sixty-first session of the General Assembly, the Special Rapporteur expressed his opinion that it is "inconceivable that some human rights do not place legal obligations on business enterprises" (see A/61/338, para. 93).

being". The Universal Declaration of Human Rights lays the foundations for the international framework for that fundamental human right, now codified in numerous national constitutions, as well as international human rights treaties, including the Convention on the Rights of the Child and the International Covenant on Economic, Social and Cultural Rights. The Guidelines also draw from other widely accepted standards, such as instruments on medicines adopted by WHO in recent years.

V. Conclusion

48. **Since this is the Special Rapporteur's last thematic report, he takes the opportunity to make some brief observations arising from his tenure between 2002 and 2008.**

Analytical and methodological issues

49. **The right to the highest attainable standard of health is complex and extensive. It encompasses medical care and the underlying determinants of health, such as water, sanitation, non-discrimination and equality. To make sense of this complexity, the Special Rapporteur has drawn from the work of many others and refined an analytical framework for "unpacking" the right to the highest attainable standard of health, with a view to making this fundamental human right easier to grasp. This framework is employed in all of the Rapporteur's thematic and country reports.**

50. **Thematic reports apply the right-to-health framework to a range of health issues, including maternal mortality, essential medicines, water and sanitation, the skills drain, sexual and reproductive health, mental disability, the health-related Millennium Development Goals, neglected diseases, international assistance and cooperation, health systems, and others. Of course, many other right-to-health issues need urgent attention, including palliative care.**

51. **Three of the Special Rapporteur's thematic reports have looked at a major methodological question: how is it possible to check whether or not a State is progressively realizing the right to health? The Special Rapporteur's third report on indicators and benchmarks sets out a human rights-based approach to health indicators.[8] Of course, this methodology can be improved. But it is now difficult to argue that there is no way of measuring the progressive realization of the right to the highest attainable standard of health.**

52. **Another report looks at impact assessments. Any modern policymaker, unless purely driven by ideology, will wish to consider the likely human rights impact of a proposed new policy or programme. The Special Rapporteur's report to the General Assembly last year sets out a methodology for right-to-health impact assessments (A/62/214).**

53. **Another chapter in the same report begins to explore the problem of prioritization. Given finite budgets, how does a Government choose between competing right-to-health priorities?**

[8] E/CN.4/2006/48.

54. **The Special Rapporteur has also begun to explore a related problem. The obligations under international law concerning the right to health are subject to maximum available resources. While some of the Special Rapporteur's reports have begun to explore this important and difficult issue, it certainly demands more attention. Of course, all international economic, social and cultural rights are subject to maximum available resources. It would be very helpful if a meeting of experts, including economists, provided guidance on what this phrase means. This would encourage a consistent interpretation and help other Special Rapporteurs as they apply this concept in their respective mandates.**

55. **Some of the Special Rapporteur's reports have begun to explore the critical issue of participation and the right to the highest attainable standard of health. This, too, however, demands more attention.**[9]

56. **Of course, all such analytical, methodological and conceptual issues are only means to an end. The real goal is implementation of the right to the highest attainable standard of health. In this respect, the Special Rapporteur hopes that his numerous country reports will be of assistance.**

Health workers, implementation and mainstreaming

57. **The classic, long-established health professions can benefit from the newer, dynamic discipline of human rights. But this is a two-way street. The right to the highest attainable standard of health cannot be realized without the interventions and insights of health workers; it cannot be realized without the expertise of those working in medicine and public health.**[10] **It is imperative that more health workers engage with human rights (see A/HRC/4/28). Also, more human rights workers must be willing to learn about health.**

58. **As the Special Rapporteur has prepared his reports, he has listened to health experts and sought to integrate their professional advice and right-to-health considerations. His report on neglected diseases in Uganda, for example, is a blend of health and human rights. It sets out, in some detail, a right-to-health approach to neglected diseases. His pending report on maternal mortality in India will be equally operational. The result of extensive consultations with health workers, his recent report on strengthening health systems integrates health and human rights considerations (A/HRC/7/11).**

59. **The General Assembly and Human Rights Council, as a large assembly consisting mainly of diplomats and lawyers, may not always be the most effective forum to discuss the right to the highest attainable standard of health. In these circumstances, the Special Rapporteur recommends that the mandate's reports should be considered not only by the General Assembly and the Human Rights Council, but also the World Health Assembly and WHO Executive Board.**

60. **Over the last six years, the Special Rapporteur has enjoyed excellent cooperation with a number of WHO staff members on a range of policy and operational issues, for which he is extremely grateful. However, to the best of**

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[9] Later this year, the University of Essex will publish a monograph on participation and the right to health.

[10] Health workers include all those developing, managing, delivering, monitoring and evaluating preventive, curative and rehabilitative health in the private and public health sectors, including traditional healers.

his knowledge, neither the World Health Assembly, nor the Executive Board, have ever considered one of his reports. Despite requests, he has never met a WHO Director General since his appointment in 2002. Of course, this would not matter if the World Health Assembly, Executive Board and others were considering the right to the highest attainable standard of health in a reasonably systematic way. But the record confirms that they are not.

61. General Assembly resolution 60/251, establishing the Human Rights Council, expressly mandates the Council to "promote the effective coordination and the mainstreaming of human rights within the United Nations system". The Special Rapporteur urges all parties to take steps to mainstream human rights in their health-related national and international policymaking.

Support and resources

62. The Special Rapporteur is extremely grateful to all those who have helped and advised him since 2002. Of course, it is impossible to mention them all. He is very grateful to United Nations agencies, in particular UNFPA, UNAIDS and a number of very supportive WHO colleagues. PAHO's support has been outstanding. He is grateful to those States that have invited him to visit, as well as the World Trade Organization that he reported on during 2005, and GlaxoSmithKline that he visited in June 2008. Throughout, the support of States, particularly Brazil and New Zealand, to the mandate has been vital. Civil society support has been indispensable. He is deeply indebted to the health workers who have patiently educated him about their profession, as well as ordinary people who have shared their time, insights and experiences — some of them painful and personal.

63. He is also very grateful to a number of funders, without whose financial assistance he could not have undertaken his duties.[11] He is extremely grateful to a small team of senior researchers and interns at the Human Rights Centre, University of Essex. Without the staff supporting his work in OHCHR nothing would have been possible. The professionalism and hard work of his colleagues at the University and OHCHR has been extraordinary.

64. Although supported by many, all have respected his independence as an expert accountable to the General Assembly and the Human Rights Council.

65. Funding for OHCHR has increased in recent years and this is very welcome indeed. But funding for special procedures remains a huge problem. What message does it send when a Special Rapporteur, with a global human rights mandate, is expected to do the job after office hours — in evenings and weekends — with the help of one very able, but overburdened, United Nations staff member? Such an arrangement is neither serious nor sustainable.

66. Nonetheless, the Special Rapporteur is very grateful to Member States for the opportunity to work with them towards the realization of one of the primary purposes of the United Nations, as set out in Article 1 of the Charter of the United Nations, the promotion and protection of human rights for all.

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[11] The Canadian International Development Agency (CIDA), European Commission, UNFPA, Joseph Rowntree Charitable Trust, Ford Foundation, Open Society Institute, British Medical Association, the International Federation of Health and Human Rights Organisations, the United Nations Educational, Scientific and Cultural Organization (UNESCO), the Special Programme for Research and Training in Tropical Diseases and WHO.

Annex

Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines

Preamble

a. Almost 2 billion people lack access to essential medicines; improving access to existing medicines could save 10 million lives each year, 4 million of them in Africa and South-East Asia.

b. Achievement of the Millennium Development Goals, such as reducing child mortality, improving maternal health, and combating HIV/AIDS, malaria and other diseases, depends upon improving access to medicines.

c. One of the Millennium Development Goal targets is, "in cooperation with pharmaceutical companies, (to) provide access to affordable essential drugs in developing countries".

d. Medical care and access to medicines are vital features of the right to the highest attainable standard of health.

e. Access to medicines depends upon effective, integrated, responsive and accessible health systems. In many countries, health systems are failing and collapsing, constituting a grave obstacle to increasing access to medicines. While a range of actors can take immediate steps to increase access to medicines, health systems must be strengthened as a matter of priority and urgency.

f. States have the primary responsibility for realizing the right to the highest attainable standard of health and increasing access to medicines.

g. In addition to States, numerous national and international actors share a responsibility to increase access to medicines.

h. As confirmed by the United Nations Global Compact, the Special Representative of the Secretary-General on human rights and transnational corporations and other business enterprises, the Committee on Economic, Social and Cultural Rights, the Business Leaders Initiative on Human Rights, and many others, the private business sector has human rights responsibilities.

i. Pharmaceutical companies, including innovator, generic and biotechnology companies, have human rights responsibilities in relation to access to medicines.

j. Pharmaceutical companies also have other responsibilities, for example, a responsibility to enhance shareholder value.

k. Pharmaceutical companies are subject to several forms of internal and external monitoring and accountability; however, these mechanisms do not usually monitor, and hold a company to account, in relation to its human rights responsibilities to enhance access to medicines.

l. Pharmaceutical companies contribute in various ways to the realization of the right to the highest attainable standard of health, such as providing individuals and communities with important information about public health issues.

Enhancing access to medicines, however, has the central place in the societal mission of pharmaceutical companies. For this reason, these non-exhaustive, interrelated Guidelines focus on the human rights responsibilities of pharmaceutical companies in relation to access to medicines.

m. The human rights responsibilities of pharmaceutical companies are not confined to the right to the highest attainable standard of health. They have human rights responsibilities, for example, regarding freedom of association and conditions of work. These human rights responsibilities, however, are not addressed in the present Guidelines.

n. While most of the Guidelines address issues that are highly relevant to all pharmaceutical companies, including innovator, generic and biotechnology companies, a few of the Guidelines address issues of particular relevance to some companies within the pharmaceutical sector.

o. The present Guidelines apply to pharmaceutical companies and their subsidiaries.

p. The present Guidelines are based on human rights principles enshrined in the Universal Declaration of Human Rights, including non-discrimination, equality, transparency, monitoring and accountability. The Constitution of the World Health Organization affirms that the "enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being". This fundamental human right is codified in numerous national constitutions, as well as international human rights treaties, including the Convention on the Rights of the Child and International Covenant on Economic, Social and Cultural Rights. Accordingly, these Guidelines are informed by some features of the right to the highest attainable standard of health, such as the requirement that medicines are of good quality, safe and efficacious. The Guidelines also draw from other widely accepted standards, such as instruments on medicines adopted by the World Health Organization.

q. For the purposes of the present Guidelines, medicines include active pharmaceutical ingredients, diagnostic tools, vaccines, biopharmaceuticals and other related health-care technologies.

r. For the purposes of the present Guidelines, neglected diseases are defined as those diseases primarily affecting those living in poverty, especially in rural areas, in low-income countries. Sometimes called tropical or poverty-related diseases, they include, for example, leishmaniasis (kala-azar), onchocerciasis (river blindness), Chagas disease, leprosy, schistosomiasis (bilharzias), lymphatic filariasis, African trypanosomiasis (sleeping sickness) and dengue. Although in recent years HIV/AIDS, tuberculosis and malaria have attracted increasing attention and resources, they may also be regarded as neglected diseases.

s. The present Guidelines adopt the World Bank definition of low-income, middle-income and high-income countries.

General

1. **The company should adopt a human rights policy statement which expressly recognizes the importance of human rights generally, and the right to**

the highest attainable standard of health in particular, in relation to the strategies, policies, programmes, projects and activities of the company.

2. **The company should integrate human rights, including the right to the highest attainable standard of health, into the strategies, policies, programmes, projects and activities of the company.**

3. **The company should always comply with the national law of the State where it operates, as well as any relevant legislation of the State where it is domiciled.**

4. **The company should refrain from any conduct that will or may encourage a State to act in a way that is inconsistent with its obligations arising from national and international human rights law, including the right to the highest attainable standard of health.**

Commentary: Formal, express recognition of the importance of human rights, and the right to the highest attainable standard of health, helps to establish a firm foundation for the company's policies and activities on access to medicines (Guideline 1). Such recognition, however, is not enough: operationalization is the challenge (Guideline 2). Many of the Guidelines signal ways in which right-to-health considerations can be operationalized and integrated into the company's activities. There are numerous national and international (including regional) legal provisions that safeguard aspects of the right to the highest attainable standard of health. It is axiomatic that they must be respected, at all times, by all pharmaceutical companies, in accordance with elementary principles of corporate good governance (Guidelines 3-4).

Disadvantaged individuals, communities and populations

5. **Whenever formulating and implementing its strategies, policies, programmes, projects and activities that bear upon access to medicines, the company should give particular attention to the needs of disadvantaged individuals, communities and populations, such as children, the elderly and those living in poverty. The company should also give particular attention to the very poorest in all markets, as well as gender-related issues.**

Commentary: Equality and non-discrimination are among the most fundamental features of international human rights, including the right to the highest attainable standards of health. They are akin to the crucial health concept of equity. Equality, non-discrimination and equity have a social justice component. Accordingly, the right to the highest attainable standard of health has a particular preoccupation with disadvantaged individuals, communities and populations, including children, the elderly and those living in poverty. Like equity, the right-to-health also requires that particular attention be given to gender. All the other Guidelines must be interpreted and applied in the light of Guideline 5, which has fundamental importance.

Transparency

6. **In relation to access to medicines, the company should be as transparent as possible. There is a presumption in favour of the disclosure of information, held by the company, which relates to access to medicines. This presumption may be rebutted on limited grounds, such as respect for the confidentiality of personal health data collected during clinical trials.**

7. **In conjunction with other pharmaceutical companies, the company should agree to standard formats for the systematic disclosure of company information and data bearing upon access to medicines, thereby making it easier to evaluate the performance of one company against another, as well as the performance of the same company over time.**

8. **Either alone or in conjunction with others, the company should establish an independent body to consider disputes that may arise regarding the disclosure or otherwise of information relating to access to medicines. That body may be the monitoring and accountability mechanism referred to in Guideline 14.**

Commentary: Transparency is another cardinal principle of international human rights, including the right to the highest attainable standard of health. It is not possible to properly understand and meaningfully evaluate access to medicines policies and practices without the disclosure of key information. There is a presumption in favour of disclosure, which may be rebutted on limited grounds (Guideline 6). Commonsense confirms that the principle of transparency not only requires that information be made publicly available, it also requires that the information be made publicly available in a form that is accessible, manageable and useful (Guideline 7). An independent, trusted and informal body should be established to consider any disputes that may arise about whether or not a particular piece of information relating to access to medicines should be disclosed (Guideline 8). That body should also provide guidance on the legitimate grounds of non-disclosure. While Guidelines 6-8 have general application to access to medicines, other Guidelines apply the cardinal principle of transparency in specific contexts, such as public policy influence, advocacy and lobbying (Guidelines17-19).

Management, monitoring and accountability

9. **The company should encourage and facilitate multi-stakeholder engagement in the formulation of its policies, programmes, projects and other activities that bear upon access to medicines. In keeping with Guideline 5, this engagement should include the active and informed participation of disadvantaged individuals, communities and populations.**

10. **The company should have a publicly available policy on access to medicines setting out general and specific objectives, time frames, reporting procedures and lines of accountability.**

11. **The company should have a governance system that includes direct board-level responsibility and accountability for its access to medicines policy.**

12. **The company should have clear management systems, including quantitative targets, to implement and monitor its access-to-medicines policy.**

13. **The company should publish a comprehensive annual report, including qualitative and quantitative information, enabling an assessment of the company's policies, programmes, projects and other activities that bear upon access to medicines.**

14. **In the context of access to medicines, internal monitoring and accountability mechanisms have a vital role to play, but they should also be supplemented by a mechanism that is independent of the company. Until such a**

mechanism is established by others, the company should establish an effective, transparent, accessible and independent monitoring and accountability mechanism that:

(a) Assesses the impact of the company's strategies, policies, programmes, projects and activities on access to medicines, especially for disadvantaged individuals, communities and populations;

(b) Monitors and holds the company to account in relation to the present Guidelines.

Commentary: All human rights, including the right to the highest attainable standard of health, require effective, transparent and accessible monitoring and accountability mechanisms. The mechanisms have a variety of forms; usually a mix of mechanisms is required. While some mechanisms are internal, others are external and independent; both types are needed. Guidelines 9-13 address the issue of internal corporate monitoring and accountability regarding access to medicines. Guideline 14 addresses the issue of an external, independent monitoring and accountability mechanism regarding access to medicines.

Corruption

15. **A company should publicly adopt effective anti-corruption policies and measures, and comply with relevant national law implementing the United Nations Convention against Corruption.**

16. **In collaboration with States, the company should take all reasonable measures to address counterfeiting.**

Commentary: Corruption is a major obstacle to the enjoyment of the right to the highest attainable standard of health, including access to medicines. Those living in poverty, for example, are disproportionately harmed by corruption because they are less able to pay for private alternatives where corruption has depleted public health services. Numerous features of the right to the highest attainable standard of health, such as transparency, monitoring and accountability, help to establish an environment in which corruption can neither thrive nor survive. In short, a right-to-health policy is also an anti-corruption policy. As emphasized in the Preamble, improving access to medicines is a responsibility shared by numerous national and international actors; Guideline 16 provides one specific example of this shared responsibility in relation to counterfeiting.[12]

Public policy influence, advocacy and lobbying

17. **The company should disclose all current advocacy and lobbying positions, and related activities, at the regional, national and international levels that impact or may impact upon access to medicines.**

18. **The company should annually disclose its financial and other support to key opinion leaders, patient associations, political parties and candidates, trade associations, academic departments, research centres and others, through which it seeks to influence public policy and national, regional and**

[12] Counterfeit drugs (medicines) are defined by WHO in FAQ's on Counterfeit Drugs, 2008.

international law and practice. The disclosure should extend to amounts, beneficiaries and channels by which the support is provided.

19. **When providing any financial or other support, the company should require all recipients to publicly disclose such support on all appropriate occasions.**

Commentary: Like many other businesses, pharmaceutical companies devote considerable resources to advocacy, lobbying and related activities. While some of these activities may impact positively on access to medicines, for example, lobbying to lower taxes on medicines, other activities may impact negatively. Guidelines have already emphasized, in general terms, the central importance of transparency in relation to access to medicines (Guidelines 6-8). Guidelines 17-19 apply this general principle of transparency to the specific context of public policy influence, advocacy and lobbying.

Quality

20. **The company should manufacture medicines that comply with current World Health Organization Good Manufacturing Practice Guidelines, as well as other appropriate international regulatory requirements for quality, safety and efficacy.**

Commentary: Guideline 20 reflects the elementary right-to-health requirement that all medicines must be of good quality, safe and efficacious.

Clinical trials

21. **A company's clinical trials should observe the highest ethical and human rights standards, including non-discrimination, equality and the requirements of informed consent. This is especially vital in those States with weak regulatory frameworks.**

22. **The company should conform to the Declaration of Helsinki on Ethical Principles for Medical Research involving Human Subjects, as well as the World Health Organization Guidelines for Good Clinical Practice.**

Commentary: The right to the highest standard of health encompasses medical ethics. Guidelines 21-22 emphasize the right-to-health responsibility of pharmaceutical companies to observe the leading international standards on ethics and clinical trials. Guidelines 9-14 emphasize the importance of effective, transparent and accessible monitoring and accountability mechanisms; these mechanisms should monitor, and hold to account, pharmaceutical companies in relation to their policies and practices on clinical trials.

Neglected diseases

23. **The company should make a public commitment to contribute to research and development for neglected diseases. Also, it should either provide in-house research and development for neglected diseases, or support external research and development for neglected diseases, or both. In any event, it should publicly disclose how much it contributes to and invests in research and development for neglected diseases.**

24. **The company should consult widely with the World Health Organization, World Health Organization/Special Programme for Research and Training in Tropical Diseases[13] and other relevant organizations, including leading civil society groups, with a view to enhancing its contribution to research and development for neglected diseases.**

25. **The company should engage constructively with key international and other initiatives that are searching for new, sustainable and effective approaches to accelerate and enhance research and development for neglected diseases.**

Commentary: By providing an incentive for pharmaceutical companies to invest in research and development, the intellectual property regime makes a major contribution to the discovery of new medicines that save lives and reduce suffering. Where there is no economically viable market, however, the incentive is inadequate and the regime fails to generate significant innovation. For this reason, a different approach is needed to address the vitally important right-to-health challenge of neglected or poverty related diseases. Defined in the Preamble, neglected diseases mainly afflict the poorest people in the poorest countries. The record shows that research and development has not addressed key priority health needs of low-income and middle-income countries. More specifically, research and development has given insufficient attention to neglected diseases. There is evidence, however, that some pharmaceutical companies are taking active measures to reverse this trend.[14] The right to the highest attainable standard of health not only requires that existing medicines are accessible, but also that much-needed new medicines are developed as soon as possible. Neglected diseases demand special attention because they tend to afflict the most disadvantaged (Guideline 5). Guideline 23 does not make the unreasonable demand that all companies provide in-house research and development for neglected diseases. Rather, all companies should make some contribution towards research and development for neglected diseases. Guidelines 23-25 signal other steps that companies should take to address the historic neglect of poverty-related diseases.

Patents and licensing

26. **The company should respect the right of countries to use, to the full, the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1994), which allow flexibility for the purpose of promoting access to medicines, including the provisions relating to compulsory licensing and parallel imports. The company should make and respect a public commitment not to lobby for more demanding protection of intellectual property interests than those required by TRIPS, such as additional limitations on compulsory licensing.**

27. **The company should respect the letter and spirit of the Doha Declaration on the TRIPS Agreement and Public Health (2001) that recognizes a State's right to protect public health and promote access to medicines for all.**

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[13] UNICEF, UNDP, World Bank, WHO Special Programme for Research and Training in Tropical Diseases.

[14] See report by Dr. Mary Moran, et al., *The New Landscape of Neglected Disease Drug Development* (The Wellcome Trust, 2005).

28. **The company should not impede those States that wish to implement the World Trade Organization Decision on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2003) by issuing compulsory licences for exports to those countries, without manufacturing capacity, encompassed by the Decision.**

29. **Given that some least developed countries are exempt from World Trade Organization rules requiring granting and enforcing patents until 2016, the company should not lobby for such countries to grant or enforce patents.**

30. **As part of its access to medicines policy, the company should issue non-exclusive voluntary licences with a view to increasing access, in low-income and middle-income countries, to all medicines. The licences, which may be commercial or non-commercial, should include appropriate safeguards, for example, requiring that the medicines meet the standards on quality, safety and efficacy set out in Guideline 20. They should also include any necessary transfer of technology. The terms of the licences should be disclosed.**

31. **As a minimum, the company should consent to National Drug Regulatory Authorities using test data (i.e., the company should waive test data exclusivity) in least developed countries and also when a compulsory licence is issued in a middle-income country.**

32. **In low-income and middle-income countries, the company should not apply for patents for insignificant or trivial modifications of existing medicines.**

Commentary: The preceding Commentary recognizes the major contribution made by the intellectual property regime to the discovery of life-saving medicines. Crucially, this regime contains various "flexibilities" and other features that are designed to protect and promote access to existing medicines. Carefully constructed, they were agreed, after protracted negotiations, by the world community of States. Because they protect and promote access to existing medicines, which is a key component of the right to the highest attainable standard of health, these "flexibilities" and other features should not be limited, diminished or compromised. Some of the key "flexibilities" and other features are addressed in Guidelines 26-29. In brief, pharmaceutical companies should not seek to limit, diminish or compromise the "flexibilities" and other features of the intellectual property regime that are designed to protect and promote access to existing medicines. Voluntary licences have a vital role to play in extending access to medicines (Guideline 30). Consistent with a company's responsibility to enhance shareholder value, commercial voluntary licences are designed to generate revenue for the patent holder. The terms of the licences should include appropriate safeguards, for example, relating to the quality, safety and efficacy of the product. Non-exclusive licences are more likely to extend access than exclusive licences. Voluntary licences respect, and depend upon, the intellectual property regime. Because data exclusivity has the potential to hinder access to medicines, companies should waive such exclusivity in all appropriate cases; while Guideline 31 identifies two occasions when the company should waive data exclusivity, there will be other occasions when a waiver is appropriate as a way of enhancing access to medicines for disadvantaged individuals, communities and populations. Access to medicines may be hindered when a company applies for a patent for improvements to an existing medicine; Guideline 32 is designed to mitigate this problem in low-income and middle-income countries.

Pricing, discounting and donations

33. **When formulating and implementing its access to medicines policy, the company should consider all the arrangements at its disposal with a view to ensuring that its medicines are affordable to as many people as possible. In keeping with Guideline 5, the company should give particular attention to ensuring its medicines are accessible to disadvantaged individuals, communities and populations, including those living in poverty and the very poorest in all markets. The arrangements should include, for example, differential pricing between countries, differential pricing within countries, commercial voluntary licences, not-for-profit voluntary licences, donation programmes, and public-private partnerships.**

34. **The arrangements should take into account a country's stage of economic development, as well as the differential purchasing power of populations within a country. The same medicine, for example, may be priced and packaged differently for the private and public sectors within the same country.**

35. **The arrangements should extend to all medicines manufactured by the company, including those for non-communicable conditions, such as heart disease and diabetes.**

36. **The company should have a board-approved policy that fully conforms to the current World Health Organization Guidelines for Drug Donations.**

37. **The company should ensure that its discount and donation schemes and their delivery channels are:**

(a) **As simple as possible, e.g., the schemes should place the minimum administrative burden on the beneficiary health system;**

(b) **As inclusive as possible, e.g., the schemes should not be confined to delivery channels that, in practice, exclude disadvantaged individuals and communities.**

38. **The company should disclose:**

(a) **As much information as possible about its pricing and discounting arrangements;**

(b) **The absolute quantity and value of its drug donations;**[15]

(c) **Where possible, the number of beneficiary patients treated each year;**

(d) **The amount of any tax benefit arising from its donations.**

Commentary: While recognizing they have a responsibility to enhance shareholder value, companies also have a human rights responsibility to extend access to medicines for all, including disadvantaged individuals, communities and populations (Guideline 5). In this context, pricing has a critical role to play. Lower prices do not necessarily mean lower profits. Sometimes the goal of enhancing access to medicines coincides with commercial interests. There are numerous arrangements that may reduce prices and increase sales, some of which are mentioned in Guidelines 33 and 34. Because the lives and health of millions are at

[15] "Value" as defined in Guideline 11, World Health Organization Guidelines for Drug Donations.

stake, companies must approach such arrangements with urgency, creativity and boldness. They cannot act alone: here is another example of the shared responsibility emphasized in the Preamble. Inventive arrangements should neither be confined to a company's "flagship" products nor a narrow range of communicable diseases (Guideline 35). Although unsustainable in the long term, a carefully constructed donation programme may extend access (Guidelines 36-37). Guidelines have already emphasized, in general terms, the central importance of transparency in relation to access to medicines (Guidelines 6-8); Guideline 38 applies this general principle of transparency to the specific context of pricing, discounting and donations.

Ethical promotion and marketing

39. **The company should take effective measures to ensure that all information bearing upon the safety, efficacy and possible side effects of a medicine are easily accessible to individuals so they can make informed decisions about its possible use.**

40. **The company should have a board-approved code of conduct and policy that fully conforms to the current World Health Organization Criteria for Medicinal Drug Promotion. In the context of this code and policy, the board should receive regular reports on its promotion and marketing activities.**

41. **The company should publicly disclose its promotional and marketing policies and activities, including costs.**

Commentary: Guidelines have already emphasized, in general terms, the central importance of transparency in relation to access to medicines (Guidelines 6-8). Guidelines 39-41 apply this general principle of transparency to the specific context of ethical promotion and marketing. Promotion and marketing give rise to a wide range of access to medicines issues, such as advertising to health professionals and the general public, packaging and labelling, and information for patients. Based on ethical considerations, the World Health Organization Criteria for Medicinal Drug Promotion provides authoritative guidance on these important matters (Guideline 40).

Public-private partnerships

42. **When participating in a public-private partnership, a company should continue to conform to these Guidelines.**

43. **If a company joins a public-private partnership, it should disclose any interest it has in the partnership's decisions and activities.**

44. **So far as these Guidelines bear upon the strategies, policies, programmes, projects and activities of public-private partnerships, they shall apply equally to such partnerships.**

45. **A company that joins a public-private partnership should take all reasonable steps to ensure that the partnership fully conforms to these Guidelines.**

Commentary: Public-private partnerships can make an important contribution to enhancing access to medicines. They are subject to right-to-health considerations corresponding to those set out in these Guidelines. Where conflicts of interest may

arise, disclosure is important, consistent with the human rights requirements of transparency.

Associations of pharmaceutical companies

46. **So far as these Guidelines bear upon the strategies, policies, programmes, projects and activities of associations of pharmaceutical companies, they shall apply equally to all such associations. The Guidelines on lobbying (Guidelines 17 and 26) and financial support (Guideline 18), for example, shall apply equally to all associations of pharmaceutical companies.**

47. **A company that is a member of an association of pharmaceutical companies should take all reasonable steps to ensure that the association fully conforms to these Guidelines.**

Commentary: A company has a responsibility to ensure that its professional associations are respectful of the right-to-health considerations set out in these Guidelines; otherwise a company could use an association as a way of avoiding its human rights responsibilities.